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MMCD 3080.2
PATENT

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Michael E. McCadden

Art Unit 1615

Serial No. 10/603,262

Filed June 25, 2003

Confirmation No. 2868

For GEL COMPOSITION FOR THE TOPICAL TREATMENT OF
RASHES, DERMATOSES AND LESIONS

September 25, 2003

COMMISSIONER FOR PATENTS
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ALEXANDRIA, VIRGINIA 22313-1450

SIR:

INFORMATION DISCLOSURE STATEMENT


Applicant submits herewith, in accordance with 37 C.F.R. 1.97 and 1.98 and MPEP 609, and in compliance with the duty of disclosure set forth in 37 C.F.R. 1.56, the attached Form PTO/SB/08A (modified) for consideration by the Patent and Trademark Office in the above-entitled application and to be made of record herein. Copies of references 1-4, 6, 8-23, 25-27 and 29-34 have not been provided in accordance with 37 C.F.R. § 1.98(d) because they are of record in prior application Serial No. 09/652,381 relied upon for an earlier filing date under 35 U.S.C. § 120.

Respectfully submitted,

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PTO/SB/08A INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) 				Complete if Known	
				Application Number	10/603,262
				Filing Date	June 25, 2003
				Confirmation Number	2868
				First Named Inventor	Michael E. McCadden
				Group Art Unit	1615
				Examiner Name	not yet assigned
Sheet	1	of	4	Attorney Docket No.	MMCD 3080.2

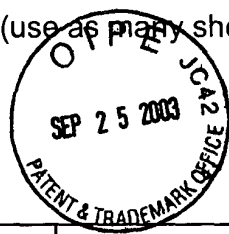
U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY		
		Number	Kind Code ² (if known)				
	1	4,569,935	A	Rosenberg et al.	02/11/1986		
	2	5,110,809	A	Wang et al.	05/05/1992		
	3	5,219,877	A	Shah et al.	06/15/1993		
	4	5,478,814	A	Packman	12/26/1995		
	5	5,883,085	A	Blank et al.	03/16/1999		
	6	5,972,920	A	Seidel	10/26/1999		
	7	6,391,282	B1	Dugger, III	05/21/2002		
FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T ⁶
		Office	Number ⁴	Kind Code ² (if known)			
	8	EP	173,478	A1	Horrobin et al.	03/05/1986	
	9	CN	1,095,615	A	Lu et al.	11/30/1994	

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	10	CN	1,111,984	A	Wu	11/22/1995	
	11	WO	92/14472	A1	Hill et al.	09/03/1992	
	12	WO	97/27862	A1	Story et al.	08/07/1997	
OTHER ART - NON PATENT LITERATURE DOCUMENTS							
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	13	M. H. WORTZEL "A Double-Blind Study Comparing the Superiority of a Combination Antifungal (Clotrimazole)/Steroidal (Betamethasone Dipropionate) Product, CUTIS, Vol. 30, (8/1982) pp. 258-261.					
	14	G. V. JAFFE et al. "An Open Trial of Clotrimazole Plus Hydrocortisone Cream in the Treatment of Napkin Dermatitis in General Practice" Pharmatherapeutica, Vol. 4, No. 5 (1985) pp. 314-318.					
	15	R. E. STOUGHTON "Are Generic Formulations Equivalent to Trade Name Topical Glucocorticoids?" Archives of Dermatology, Vol. 123 (10/1987) pp. 1312-1314.					
	16	R. E. STOUGHTON "Bioassay System for Formulations of Topically Applied Glucocorticosteroids" Archives of Dermatology, Vol. 106 (12/1972) pp. 825-827.					
	17	D. B. JACKSON et al. "Bioequivalence (bioavailability) of General Topical Corticosteroids" Journal of the American Academy of Dermatology, Vol. 20, No. 5, Pt. 1 (5/1989) pp. 791-796.					

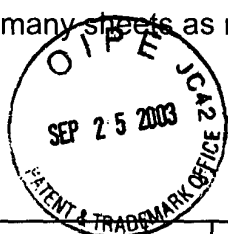
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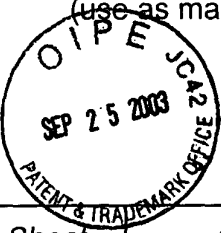
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	18	C. A. GUZZO et al. "Chapter 64, Dermatological Pharmacology" Goodman & Gilman's The Pharmacological Basis of Therapeutics, 9th Ed., McGraw-Hill (1996) pp. 1593-1598.	
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	21	T. B. FITZPATRICK et al. "Dermatology In General Medicine, Vol. II, 4th Ed., McGraw-Hill, Inc., (1993) pp. 2444-2447 and 2847.	
	22	E.G.V. EVANS et al. "Does Naftifine Have Anti-Inflammatory Properties? A Double-blind Comparative Study With 1% Clotrimazole/1% Hydrocortisone in Clinically Diagnosed Fungal Infection of the Skin" British Journal of Dermatology, Vol. 129 (1993) pp. 437-442.	
	23	S. K. HEBEL et al. "Drug Facts and Comparisons" Facts and Comparisons, St. Louis, A Wolters Kluwer Company (1/2000) pages ii, 1658, 1659, 1684.	
	24	"Facts and Comparisons, on Aveeno® anti-itch", by Rydelle, revised May 1992, pp. 564a.	
	25	S. LEVY "Latest Switch - Lamisil - Offers to Get it Done Faster" Drug Topics, 4/19/99, pp. 72.	
	26	K. A. ARNDT et al. "Manual of Dermatologic Therapeutics" 5th Ed., Little, Brown & Co., pp. 49, 290, 309.	
	27	A. W. McKENZIE et al. "Method for Comparing Percutaneous Absorption of Steroids" Archive of Dermatology, Vol. 86, (1962) pp. 608-610.	
	28	"Physician's Desk Reference, on Caldryl®", by Pfizer, obtained from PDR on-line.	

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	29	V. A. PLACE et al. "Precise Evaluation of Topically Applied Corticosteroid Potency" Archives of Dermatology, Vol. 101 (5/1970) pp. 531-537.	
	30	H. I. KATZ et al. "SCH 370 (Clotrimazole-Betamethasone Dipropionate) Cream in Patients with Tinea Cruris or Tinea Corporis" Vol. 34 (8/1984) pp. 183-188.	
	31	P. WALSH et al. "Schering, Lotrisone" Physicians' Desk Reference PDR 55ed 2001, pp. 2912-2914.	
	32	A. R. W. BOWRING et al. "The Treatment of Napkin Dermatitis: a Double-Blind Comparison of Two Steroid-Antibiotic Combinations" Pharmatherapeutica, Vol. 3, No. 9 (1984) pp. 613-617.	
	33	"USP 24, NF 19" U.S. Pharmacopeia & National Formulary, The United States Pharmacopeial Convention, Inc. 12601 Twinbrook Parkway, Rockville, MD (1999) pp. 273-274, 1768-1769.	
	34	R. E. STOUGHTON "Vasoconstrictor Activity and Percutaneous Absorption of Glucocorticosteroids" Archives of Dermatology, Vol. 99 (6/1969) pp. 753-756.	

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